

PATIENT GROUP DIRECTION (PGD)

Supply of Naloxone (Prenoxad®)
By Alcohol Care Team (ACT) and Mental Health Liaison Team (MHLT)
at Royal Derby Hospital

Documentation details

Reference no:	UHDB303
Version no:	1
Valid from:	22/08/2024
Review date:	22/02/2027
Expiry date:	21/08/2027

Change history

Version number	Change details	Date
1	New PGD based on a PGD developed by system partners at Derbyshire Healthcare NHS Foundation Trust.	July 2024

Glossary

Abbreviation	Definition
ACT	Alcohol Care Team
DHCFT	Derbyshire Healthcare NHS Foundation Trust (Mental Health Services)
MHLT	Mental Health Liaison Team

1. PGD template development (PGD Working Group)

PGD Working Group Membership (minimum requirement of consultant, pharmacist and a registered professional who can work under a PGD, or manages the staff who do). If this is a review of existing PGD, replace previous names with the individuals involved for this version

Name	Designation
Alison Marsh-Davies	Advanced Pharmacist - Mental Health Liaison Team
Dr Kaathan Jawahar	Consultant - Mental Health Liaison Team
Manzar Maqsood	Advanced Pharmacist - Acute Medicine
Vickie Tang	Advanced Pharmacist - Acute Medicine

Where an antimicrobial is included, confirm the name, designation and date of the antimicrobial pharmacist who has reviewed this version

Name of antimicrobial pharmacist	Designation	Date Reviewed
n/a	n/a	n/a

2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

University Hospitals of Derby & Burton NHS Foundation Trust authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
<p>Derbyshire Healthcare NHS Foundation Trust professionals who are contracted to deliver:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Mental Health Liaison Team services <input type="checkbox"/> Alcohol Care Team services <p>And who meet the requirements detailed in Section 3 (Characteristics of Staff)</p>
Limitations to authorisation
<p>Nil additional</p>

Organisational Authorisation (legal requirement).			
Role	Name	Sign	Date
Medicines Safety Officer	James Hooley	Signed copy held by Pharmacy	22/08/2024

Additional signatories (required as per legislation and locally agreed policy)			
Role	Name	Sign	Date
Clinical Pharmacist from PGD working group	Manzar Maqsood	Signed copy held by Pharmacy	01/08/2024
Consultant Psychiatrist - MHLT	Dr Kaathan Jawahar	Signed copy held by Pharmacy	01/08/2024
Senior Registered Professional representing users of the PGD	Denise Garton	Signed copy held by Pharmacy	14/08/2024

Local enquiries regarding the use of this PGD may be directed to UHDB.PGDgovernance@nhs.net

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD.

3. Characteristics of staff

Qualifications and professional registration	NMC registered nurse with a current contract of employment with Derbyshire Healthcare NHS Foundation Trust who has undergone relevant training around provision of take-home naloxone hydrochloride (Prenoxad).
Initial training	<ul style="list-style-type: none"> <input type="checkbox"/> Completion of Essential-to-role training for PGDs provided by either DHFT or UHDB (UHDB training via My Learning Passport) <input type="checkbox"/> Individual has read and understood full content of this PGD and signed authorisation (section 7) <input type="checkbox"/> Resuscitation skills and overdose management <input type="checkbox"/> Naloxone overdose and DHCFT training <p>The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate training and successfully completed the competencies to undertake clinical assessment of individuals leading to diagnosis of the conditions listed.</p>
Competency assessment	<p>Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions</p> <p>Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with either authorising manager (section 7) or the manager within the PGD working group (section 1) so that further training can be provided as required.</p>
Ongoing training and competency	<p>Annual update of resuscitation skills and overdose management</p> <p>Annual update on product information and the use of this Naloxone PGD and training</p>
<p>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.</p>	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Supply of take-home naloxone hydrochloride (Prenoxad) for UHDB patients under the care of Derbyshire Healthcare NHS Foundation Trust ACT or MHLT, not open to other services for provision of naloxone, to reduce the risk of fatality in the event of an opioid overdose.
Criteria for inclusion	<ul style="list-style-type: none"> <input type="checkbox"/> Consent gained. <input type="checkbox"/> Service users over 18 years old <input type="checkbox"/> Service users identified to be at risk of future episodes of opioid overdose. <input type="checkbox"/> Completed relevant DHCFT-approved training (e.g. approved video training)
Criteria for exclusion	<ul style="list-style-type: none"> <input type="checkbox"/> Consent not gained. <input type="checkbox"/> Service user under 18 years of age <input type="checkbox"/> Reviewed as not appropriate for take-home naloxone. <input type="checkbox"/> Refusal to complete the relevant training session. <input type="checkbox"/> Service user declined supply of take-home naloxone. <input type="checkbox"/> Known hypersensitivity to naloxone or any component of the preparation.
Cautions including any relevant action to be taken	<ul style="list-style-type: none"> <input type="checkbox"/> It should be administered cautiously to patients who have received large doses of opioids or to those physically dependent on opioids since too rapid reversal of opioid effects by Prenoxad Injection may precipitate an acute withdrawal syndrome in such patients. <input type="checkbox"/> Prenoxad Injection is not effective against respiratory depression caused by non-opioid drugs. Reversal of buprenorphine-induced respiratory depression may be incomplete. If an incomplete response occurs, respiration should be mechanically assisted. <input type="checkbox"/> Cardiovascular disease or those receiving cardiotoxic drugs (serious adverse cardiovascular effects reported) - Refer to a prescriber if unsure on the balance of risk versus benefit.
Action to be taken if the patient is excluded	<ul style="list-style-type: none"> <input type="checkbox"/> Record reasons for exclusion in an individual's clinical record <input type="checkbox"/> Advise individuals on alternative treatment. <input type="checkbox"/> Refer to another clinician or prescriber if appropriate
Action to be taken if the patient or carer declines treatment	<ul style="list-style-type: none"> <input type="checkbox"/> If appropriate, acknowledge the service user's right to decline treatment, ensuring that they understand the risks and any available alternative approaches. Refer to a doctor if applicable and seek further advice where appropriate. <input type="checkbox"/> Document advice given. <input type="checkbox"/> Advise individual on alternative treatment.
Arrangements for referral for medical advice	Refer to the appropriate clinician or prescriber in the care pathway

5. Description of treatment

Name, strength & formulation of drug	Naloxone hydrochloride (Prenoxad) 2mg/2ml solution of injection pre-filled syringe
Legal category	POM

Route / method of administration	Intramuscular injection
Indicate any off-label use (if relevant)	Not applicable
Dose and frequency of administration	<p>Maximum ONE 2mg pre-filled syringe to be supplied to service user to take home.</p> <p>Naloxone is short acting. Emergency services (ambulance) must be called when opioid overdose is suspected, and Naloxone is administered. Naloxone can provide sufficient improvement until the ambulance arrives and further medical assistance can be offered. Further Naloxone doses may be given by emergency services upon arrival.</p> <p>400 micrograms (one dose) every 2–3 minutes, each dose given in subsequent resuscitation cycles if patient not breathing normally, continue until consciousness regained, breathing normally, medical assistance available, or contents of syringe used up; to be injected into deltoid region or anterolateral thigh</p>
Duration of treatment	<p>One single episode as documented above under dose and frequency of administration.</p> <p>Emergency services (ambulance) must be called when opioid overdose suspected, and naloxone is administered.</p>
Quantity to be supplied (leave blank if PGD is administration ONLY)	<p>Take home Naloxone will be supplied as pre-packed Naloxone kit. This will be an overlabelled pack ("TTO pack") which will require patient name and date adding by the practitioner working under this PGD. The pack will contain:</p> <ul style="list-style-type: none"> □ 1 x 2ml pre-filled syringe (containing Naloxone Hydrochloride 1mg/1ml) □ 2 x 23G 1¼" needles for intramuscular injection <p>1 x product instruction sheet must be issued.</p>
Storage	<p>Naloxone (Prenoxad) does not require any special storage precautions, but the pre-filled syringe must be kept in the original plastic box in order to protect from light.</p> <p>Service users must be advised to keep the take-home Naloxone out of reach of children and pets and encouraged to return for replacement dose should they have used or lost the medication or when it has expired. Service users must be advised in the safe disposal of needles following the use of the take home Naloxone.</p>
Drug interactions	<p>A detailed list of drug interactions is available in the Summary of Product Characteristics: Prenoxad 1mg/ml Solution for Injection in a pre-filled syringe - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)</p>
Adverse reactions	<p>The following possible adverse effects are commonly reported with naloxone hydrochloride (but may not reflect all reported adverse effects):</p>

	<ul style="list-style-type: none"> <input type="checkbox"/> Arrhythmias <input type="checkbox"/> Dizziness <input type="checkbox"/> Headache <input type="checkbox"/> Hypertension or hypotension <input type="checkbox"/> Nausea and vomiting <p>A detailed list of adverse reactions is available in the Summary Prenoxad 1mg/ml Solution for Injection in a pre-filled syringe - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk)</p>
Management of and reporting procedure for adverse reactions	<ul style="list-style-type: none"> <input type="checkbox"/> Healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk <input type="checkbox"/> Record all adverse drug reactions (ADRs) in the individual's clinical record. <input type="checkbox"/> Report via organisation incident policy. <input type="checkbox"/> If anaphylaxis management may be required include this information here (e.g. adrenaline to be held/resuscitation team details)
Written information to be given to patient or carer	<p>Give marketing authorisation holder's product information leaflet (PIL) provided with the product.</p> <p>Service users and relevant family/friends should have training on use via the DHCFT approved training video. This is done prior to issuing the PGD.</p>
Patient advice / follow up treatment	<p>Inform the individual/carer of possible side effects and their management.</p> <p>The individual/carer should be advised to seek medical advice in the event of an adverse reaction.</p>
Records	<p>Record administration of Naloxone PGD on Lorenzo</p> <p>Record in SystemOne:</p> <ul style="list-style-type: none"> <input type="checkbox"/> identified risk of future opioid overdose as agreed to MDT and substance misuse <input type="checkbox"/> that valid informed consent was given <input type="checkbox"/> date training provided and completed with service user and with which healthcare professional <input type="checkbox"/> name of medication supplied/administered. <input type="checkbox"/> date of supply/administration <input type="checkbox"/> quantity supplied/administered. <input type="checkbox"/> batch number and expiry date (if applicable) <input type="checkbox"/> advice given, including advice given if excluded or declines treatment. <input type="checkbox"/> supplied via Patient Group Direction (PGD) <p>If the patient has declined supply of take-home naloxone or not completed the training this needs to be clearly documented in SystemOne including alternative approaches considered.</p> <p>Records should be signed and dated (or a password controlled e-records).</p> <p>All records should be clear, legible, and contemporaneous.</p>

	A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.
--	--

6. Key references

Key references	<ul style="list-style-type: none"> □ DHCFT Guidance for Psychiatric Inpatient Settings on the Provision of Take-Home Naloxone. Review date: October 2026 □ Electronic Medicines Compendium Prenoxad 1mg/ml Solution for Injection in a pre-filled syringe - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) □ Electronic BNF Naloxone hydrochloride Drugs BNF NICE □ NICE Medicines practice guideline “Patient Group Directions” https://www.nice.org.uk/guidance/mpg2 □ When and how to give Prenoxad Injection □ How to – Naloxone □ Prenoxad-Clients-Guide.pdf (prenoxad injection.com) □ Harm Reduction. What you need to know! □ Overdose prevention. What you need to know! □ Heroin What you need to know! □ Fentanyl What you need to know!
----------------	--

7. Registered health professional authorisation sheet

PGD Name [version]: Naloxone (Prenoxad®) [v1]

PGD ref: UHDB303

Valid from: 22/08/2024

Expiry date: 21/08/2027

Before signing check that the document you have read is published on Koha or is an in-date hard-copy with all necessary authorisations signed in section 2. The Name/Version/Ref of the document you have read MUST match this authorisation form.

Registered health professional

By signing this patient group direction you are indicating that

- a) You agree to and understand all content and commit to only work within this framework.
- b) You have completed any core PGD e-Learning or training records on My Learning Passport or within your department.
- c) You meet the staff characteristics and have completed any additional learning/competency outlined in Section 3 of this PGD.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager / Assessor

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of University Hospitals of Derby & Burton NHS Foundation Trust for the above named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet must be retained by a manager in the clinical department where the PGD is in-use to serve as a record of those registered health professionals authorised to work under this PGD.